Complete Summary

GUIDELINE TITLE

Colorectal cancer screening clinical practice guideline.

BIBLIOGRAPHIC SOURCE(S)

Kaiser Permanente Care Management Institute. Colorectal cancer screening clinical practice guideline. Oakland (CA): Kaiser Permanente Care Management Institute; 2006 Nov. 74 p. [96 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Colorectal cancer

GUIDELINE CATEGORY

Prevention
Risk Assessment
Screening

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Internal Medicine

Obstetrics and Gynecology
Oncology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To assist primary care and specialist physicians and other health care professionals in counseling asymptomatic adults about colorectal cancer screening procedures

TARGET POPULATION

Asymptomatic adults aged 18 and older at average or increased risk of colorectal cancer

Note: This guideline addresses colorectal cancer screening in the general, symptomatic adult population seen in the primary care setting. It does not address screening and/or surveillance in adults with a personal history of colorectal cancer or inflammatory bowel disease, or a family history of hereditary colorectal cancer syndromes, such as familial adenomatous polyposis, Gardner's syndrome, and hereditary nonpolyposis colon cancer (Lynch syndrome).

INTERVENTIONS AND PRACTICES CONSIDERED

1. Risk assessment
2. Screening of asymptomatic adults using one of the following:
    - Three-sample guaiac fecal occult blood test (FOBT)
    - Flexible sigmoidoscopy
    - High-sensitivity FOBTs (three-sample hemoccult SENSA) and single-sample immunochemical fecal occult blood test
    - Combined three-sample FOBT and flexible sigmoidoscopy
    - Colonoscopy
3. Consideration of frequency of colorectal cancer screening
4. Consideration of age to begin and end colorectal cancer screening
5. Referral to specialist (when indicated)

The following tests were considered but not recommended: air-contrast barium enema, virtual colonoscopy and fecal DNA.

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of screening tests
- Incidence of colorectal cancer
- Morbidity and mortality from colorectal cancer
- Adverse effects of tests

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Guidelines are developed using an "evidence-based methodology" that involves a systematic literature search, critical appraisal of the research design and statistical results of relevant studies, and grading of the sufficiency (quantity, quality, consistency, and relevancy) of the evidence for drawing conclusions.

During the guideline development process, the Guideline Development Team reviews evidence published in peer-reviewed scientific journals, existing evidence-based guidelines, and consensus statements from external professional societies and government health organizations, and clinical expert opinion of Kaiser Permanente regional specialty groups.

For details of the literature search, including databases searched and search terms for each clinical question, see the original guideline document.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Refer to Table 2 in the Appendix of the original guideline document for the system for grading the strength of a body of evidence.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Guideline Development Team performed systematic reviews of the medical literature on each of the clinical questions identified by the workgroup.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

To develop guidelines, the Project Management Team works with a multidisciplinary team of physicians and other health care professionals. This Guideline Development Team (GDT) consists of a core, multidisciplinary group of physicians representing those medical specialties most affected by the guideline topic. The physicians on the GDT are nominated by the National Guideline Directors from their region.

During the guideline development process, the GDT reviews evidence published in peer-reviewed scientific journals, existing evidence-based guidelines and consensus statements from external professional societies and government health organizations, and clinical expert opinion of KP regional specialty groups. The GDT develops the guideline and team members facilitate information exchange in both directions on behalf of the Region that they represent. This process should include obtaining the buy-in of the local champions regarding the guideline so that it will be implemented once published.

To keep current with changing medical practices, all guidelines are reviewed, and, if appropriate, revised at least every two years. To update the Colorectal Cancer Screening Guideline, released in November 2006, a multidisciplinary, interregional GDT met in June 2006 to define the scope of the guideline. The Project Management Team then performed systematic reviews of the medical literature on each of the clinical questions identified by the GDT, assembled the evidence, and developed draft recommendations for review by the GDT All of the recommendations and supporting evidence were reviewed by the GDT in depth through a series of conference calls and in-person meetings in September and October 2006. The National Guideline Directors reviewed and sponsored the guideline in November 2006.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendations are classified as either "evidence-based (A-D, I)" or "consensus-based."

- *Evidence-based*: sufficient number of high-quality studies from which to draw a conclusion, and the recommended practice is consistent with the findings of the evidence. A recommendation can also be considered "evidence-based" if there is insufficient evidence and no practice is recommended.
- *Consensus-based*: insufficient evidence and a practice is recommended based on the consensus or expert opinion of the Guideline Development Team.

Label and Language of Recommendations*

Label	Evidence-Based Recommendations
Evidence-based (A)	**Language**: [a] The intervention is strongly recommended for eligible patients.

Label	Evidence-Based Recommendations
	Evidence: The intervention improves important health outcomes, based on good evidence, and the Guideline Development Team (GDT) concludes that benefits substantially outweigh harms and costs. **Evidence Grade**: Good.
Evidence-based (B)	**Language**: [a] The intervention is recommended for eligible patients. **Evidence**: The intervention improves important health outcomes, based on 1) good evidence that benefits outweigh harms and costs; or 2) fair evidence that benefits substantially outweigh harms and costs. **Evidence Grade**: Good or Fair.
Evidence-based (C)	**Language**: [a] No recommendation for or against routine provision of the intervention. (At the discretion of the GDT, the recommendation may use the language "option," but must list all the equivalent options.) **Evidence**: Evidence is sufficient to determine the benefits, harms, and costs of an intervention, and there is at least fair evidence that the intervention improves important health outcomes. But the GDT concludes that the balance of the benefits, harms, and costs is too close to justify a general recommendation. **Evidence Grade**: Good or Fair.
Evidence-based (D)	**Language**: [a] Recommendation against routinely providing the intervention to eligible patients. **Evidence**: The GDT found at least fair evidence that the intervention is ineffective, or that harms or costs outweigh benefits. **Evidence Grade**: Good or Fair.
Evidence-based (I)	**Language**: [a] The evidence is insufficient to recommend for or against routinely providing the intervention. (At the discretion of the GDT, the recommendation may use the language "option," but must list all the equivalent options.) **Evidence**: Evidence that the intervention is effective is lacking, of poor quality, or conflicting and the balance of benefits, harms, and costs cannot be determined. **Evidence Grade**: Insufficient.
Consensus-based	**Language**: [a] The language of the recommendation is at the discretion of the GDT, subject to approval by the National Guideline Directors. **Evidence**: The level of evidence is assumed to be "Insufficient" unless otherwise stated. However, do not use the A, B, C, D, or I labels which are only intended to be used for evidence-based recommendations. **Evidence Grade**: Insufficient, unless otherwise stated.
For the rare consensus-based recommendations which have "Good" or "Fair" evidence, the evidence must support a different recommendation, because if the	

Label	Evidence-Based Recommendations
evidence were good or fair, the recommendation would usually be evidence-based. In this kind of consensus-based recommendation, the evidence grade should point this out (e.g., "Evidence Grade: Good, supporting a different recommendation").	

[a] All statements specify the population for which the recommendation is intended.

*Recommendations should be labeled and given an evidence grade. The evidence grade should appear in the rationale. Evidence is graded with respect to the degree it supports the specific clinical recommendation. For example, there may be good evidence that Drugs 1 and 2 are effective for Condition A, but no evidence that Drug 1 is more effective than Drug 2. If the recommendation is to use either Drug 1 or 2, the evidence is good. If the recommendation is to use Drug 1 in preference to Drug 2, the evidence is insufficient.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The National Guideline Directors reviewed and sponsored the guideline in November 2006.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the levels of evidence (evidence-based A-D, I and consensus-based) are provided at the end of the "Major Recommendations" field.

Problem Formulation #1: Factors Associated With An Increased Risk of Colorectal Cancer in the General Population

1A. A significant family history is associated with an increased risk of colorectal cancer. (*See Problem Formulation #5, below, for screening recommendations and specific definition of family history*.) (**Evidence-based: A**)

1B. Advancing age is associated with an increased risk of colorectal cancer. (**Evidence-based: B**)

1C. There is fair evidence that African-Americans are at increased risk for colorectal cancer compared with Whites. However, the magnitude of the increased risk is too small to warrant incorporation into screening recommendations.* (**Evidence-based: C**)

1D. There is fair evidence that a family history of advanced adenomas presenting before age 60 is associated with an increased risk of colorectal cancer. However, the magnitude of the increased risk is too small to warrant incorporation into screening recommendations. (**Evidence-based: C**)

1E. There is insufficient evidence for or against the association of gender with an increased risk of colorectal cancer. (**Evidence-based: I**)

*For African-Americans, special efforts should be made to ensure that screening occurs using any of the accepted screening modalities, as well as consideration of earlier screening than for other racial groups. Observational national data demonstrate an increased risk of colorectal cancer and a more advanced stage of disease at diagnosis among African-Americans than among Whites. It is not clear whether this disparity is due to differences in the biological behavior of colorectal cancer in African-Americans, differences in socioeconomic status, or differences in access to care.

Problem Formulation #2: Effectiveness of Colorectal Cancer Screening Tests

2A. Colorectal cancer screening is strongly recommended for all asymptomatic, average-risk adults. (**Evidence-based: A**)

Any of the following tests are acceptable for colorectal cancer screening in asymptomatic, average-risk adults:*

- **2B**. A three-sample guaiac fecal occult blood test (FOBT) is recommended provided that patients are informed of the potential risks associated with false-positive and false-negative test results, as well as the need for prompt follow-up of a positive test result. (**Evidence-based: B**)
- **2C**. Flexible sigmoidoscopy is recommended provided that patients are informed that the test has a small risk of complications and is not a complete examination of the entire colon. (**Evidence-based: B**)
- **2D**. High-sensitivity fecal occult blood tests (three-sample Hemoccult SENSA) and single-sample immunochemical fecal occult blood tests (iFOBT) are options for screening, provided that patients are informed of the potential risks associated with false-positive and false-negative test results, as well as the need for prompt follow-up of a positive test result.** (**Consensus-based**)
- **2E**. A combination of three-sample fecal occult blood test and flexible sigmoidoscopy is an option for screening provided that patients are informed of the potential risks associated with false-positive and false-negative FOBT results, as well as the need for prompt follow-up of a positive FOBT result. (**Consensus-based**)

The following additional screening tests either are not recommended or are less-preferred options for screening. However, an adult who has had one of the tests is considered screened. Follow-up screening using a preferred option is recommended.

- **2F**. Colonoscopy is a less-preferred option for screening because of the increased risk of serious complications and the existence of other evidence-based options for screening average-risk adults.** (**Evidence-based: I**).

- **2G**. There is insufficient evidence to recommend for or against the use of air contrast barium enema as a screening strategy for average-risk adults. (**Evidence-based: I**)
- **2H**. Virtual colonoscopy is not recommended as a screening strategy for average-risk adults.*** (**Consensus-based**)
- **2I**. Fecal DNA is not recommended as a screening strategy for average-risk adults.*** (**Consensus-based**)

*There is insufficient evidence to choose one screening test over another.
**If a patient has had a normal colonoscopy within the last 10 years, there is insufficient evidence that supplemental FOBT adds any incremental benefit.
***Please note that fecal DNA testing and virtual colonoscopy are not listed as "appropriate screening tests" in 2007 Health Plan Employer Data and Information Set (HEDIS) specifications for colorectal cancer screening, and therefore regions may choose to screen members with other appropriate tests.

Problem Formulation #3: Frequency of Colorectal Cancer Screening

The following intervals for colorectal cancer screening in asymptomatic, average-risk adults are recommended*:

- **3A**. Three-sample guaiac fecal occult blood test (FOBT): every 1-2 years** (**Evidence-based: B**)
- **3B**. Flexible sigmoidoscopy: at least every 10 years** (**Consensus-based**)
- **3C**. Three-sample high-sensitivity guaiac FOBT and single-sample immunochemical FOBT: every 1-2 years*** (**Consensus-based**)

The following additional screening tests are either less-preferred options or not recommended for screening average-risk adults. However, if these tests are performed, then the recommended intervals are as indicated below. Follow-up screening using a preferred option is recommended.

- **3D**. Colonoscopy: every 10 years*** (**Consensus-based**)
- **3E**. Air contrast barium enema: every 5 years*** (**Consensus-based**)
- **3F**. Virtual colonoscopy: every 10 years[#] (**Consensus-based**)
- **3G**. Fecal DNA: every 5 years[#] (**Consensus-based**)

*The Guideline Development Team (GDT) recognizes that these screening intervals differ from current HEDIS measures. Some regions may choose to offer screening at more frequent intervals. HEDIS intervals are as follows: FOBT (annual), flexible sigmoidoscopy (every 5 years), air contrast barium enema (every 5 years), colonoscopy (every 10 years).
**There is no evidence on the effectiveness of various screening intervals for combined FOBT and flexible sigmoidoscopy.
***There is insufficient evidence to recommend for or against these modalities for screening average-risk adults (see Problem Formulation 2, above).
#These modalities are not recommended for screening average-risk adults (see Problem Formulation 2. above).

Problem Formulation #4: Age to Begin and End Colorectal Cancer Screening

In the absence of sufficient evidence, the following ages at which to begin and end colorectal cancer screening in asymptomatic average-risk adults are recommended:

- **4A**. Initiation of screening is recommended at age 50. (**Consensus-based**)
- **4B**. Discontinuation of screening is generally recommended at age 80. The decision to discontinue screening should be based on physician judgment, patient preference, the increased risk of complications in older adults, and existing comorbidities. (**Consensus-based**)

Problem Formulation #5: Screening In Adults At Increased Risk of Colorectal Cancer

Family History

Colonoscopy screening beginning at age 40, or 10 years younger than the earliest diagnosis in the first-degree relative, is recommended in adults with the following significant family history of colorectal cancer:

- **5A**. One first-degree relative (parent, sibling, or offspring) with a diagnosis of colorectal cancer at age 60 or younger.* (**Consensus-based**)
- **5B**. Two or more first-degree relatives diagnosed with colorectal cancer at any age.* (**Consensus-based**)

5C. In the absence of sufficient evidence, colonoscopy screening for this population is recommended at least every 10 years. Based on individual patient characteristics and clinical scenarios, more frequent screening may be appropriate. (**Consensus-based**)

5D. For evaluation and follow-up of hereditary colorectal cancer syndromes and inflammatory bowel disease, referral to Gastroenterology is recommended.** (**Consensus-based**)

Age, Race or Ethnicity, and Gender

5E. Special efforts are recommended to ensure screening in adults aged 60 to 75, using any of the accepted screening modalities. If colonoscopy is used for screening in adults without a family history of colorectal cancer, it is most likely to be beneficial for fit adults aged 60 to 75, where the incidence of proximal cancers is higher and the balance of benefits vs. harms is favorable. Because colonoscopy requires procedural sedation and vigorous bowel preparation and has a higher rate of complications than other tests, counseling on the benefits and risks of screening is recommended, especially in older adults with comorbidities. (**Consensus-based**)

5F. Special efforts are recommended to ensure that screening occurs among African-Americans, using any of the accepted screening modalities.*** (**Consensus-based**)

5G. There is insufficient evidence to recommend for or against differential screening strategies based on gender.[#] (**Evidence-based: I**)

*There is fair evidence that a family history of advanced adenomas presenting before age 60 is associated with an increased risk of colorectal cancer. However, the magnitude of the increased risk is too small to warrant incorporation into screening recommendations. (**Evidence-based: C**)
**Hereditary syndromes include familial adenomatous polyposis, Gardner's syndrome, and hereditary

nonpolyposis colon cancer (Lynch syndrome).
***For African-Americans, special efforts should be made to ensure that screening occurs using any of the accepted screening modalities, as well as consideration of earlier screening as compared with other racial groups. Observational national data demonstrate an increased risk of colorectal cancer and a more advanced stage of disease at diagnosis among African-Americans than among Whites. It is not clear whether this disparity is due to differences in the biological behavior of colorectal cancer in African-Americans, differences in socioeconomic status, or differences in access to care.
[#]Women are at slightly lower risk than men for colorectal cancer, at the same age. However, this risk difference is not significant enough to justify a different approach to colorectal cancer screening for men and women.

Definitions:

Label and Language of Recommendations

Label	Evidence-Based Recommendations
Evidence-based (A)	**Language**: [a] The intervention is strongly recommended for eligible patients. **Evidence**: The intervention improves important health outcomes, based on good evidence, and the Guideline Development Team (GDT) concludes that benefits substantially outweigh harms and costs. **Evidence Grade**: Good.
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Evidence-based (C)	**Language**: [a] No recommendation for or against routine provision of the intervention. (At the discretion of the GDT, the recommendation may use the language "option," but must list all the equivalent options.) **Evidence**: Evidence is sufficient to determine the benefits, harms, and costs of an intervention, and there is at least fair evidence that the intervention improves important health outcomes. But the GDT concludes that the balance of the benefits, harms, and costs is too close to justify a general recommendation. **Evidence Grade**: Good or Fair.
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Label	Evidence-Based Recommendations
	equivalent options.) **Evidence**: Evidence that the intervention is effective is lacking, of poor quality, or conflicting and the balance of benefits, harms, and costs cannot be determined. **Evidence Grade**: Insufficient.
Consensus-based	**Language**: [a] The language of the recommendation is at the discretion of the GDT, subject to approval by the National Guideline Directors. **Evidence**: The level of evidence is assumed to be "Insufficient" unless otherwise stated. However, do not use the A, B, C, D, or I labels which are only intended to be used for evidence-based recommendations. **Evidence Grade**: Insufficient, unless otherwise stated.
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[a] All statements specify the population for which the recommendation is intended.

*Recommendations should be labeled and given an evidence grade. The evidence grade should appear in the rationale. Evidence is graded with respect to the degree it supports the specific clinical recommendation. For example, there may be good evidence that Drugs 1 and 2 are effective for Condition A, but no evidence that Drug 1 is more effective than Drug 2. If the recommendation is to use either Drug 1 or 2, the evidence is good. If the recommendation is to use Drug 1 in preference to Drug 2, the evidence is insufficient.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation, but the evidence underlying the recommendations are drawn from randomized controlled trials, meta-analyses, and existing systematic reviews. In cases where the data was inconclusive, inconsistent, or non-existent, recommendations were based on the consensus opinion of the group.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate colorectal cancer screening

- Early detection of colorectal cancer in the general population; asymptomatic, average-risk adults; and increased-risk adults
- Reduced morbidity and mortality from colorectal cancer

POTENTIAL HARMS

- Inconvenience, anxiety, and adverse effects of tests (e.g., discomfort, pain, bowel perforation, bleeding)
- Unnecessary invasive tests due to false-positive test results
- False reassurance from false-negative test results

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These guidelines are informational only. They are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by practitioners, considering each patient's needs on an individual basis.
- Guideline recommendations apply to populations of patients. Clinical judgment is necessary to design treatment plans for individual patients.
- This guideline addresses colorectal cancer screening recommendations in the general, asymptomatic adult population seen in the primary care setting. It does not address screening and/or surveillance in adults with a personal history of colorectal cancer or inflammatory bowel disease, or a family history of hereditary colorectal cancer syndromes, such as familial adenomatous polyposis, Gardner's syndrome, and hereditary nonpolyposis colon cancer (Lynch syndrome).

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Kaiser Permanente Care Management Institute. Colorectal cancer screening clinical practice guideline. Oakland (CA): Kaiser Permanente Care Management Institute; 2006 Nov. 74 p. [96 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Nov

GUIDELINE DEVELOPER(S)

Kaiser Permanente Care Management Institute - Managed Care Organization

SOURCE(S) OF FUNDING

Kaiser Permanente Care Management Institute

GUIDELINE COMMITTEE

Colorectal Cancer Screening Guideline Development Team

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: None available

Print copies: Available from the Kaiser Permanente Care Management Institute, One Kaiser Plaza, 16th Floor, Oakland, CA 94612

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Kaiser Permanente Care Management Institute. Colorectal cancer screening. Clinical practice guideline. Summary of recommendations. Oakland (CA): Kaiser Permanente Care Management Institute; 2006 Nov. 3 p.
- Kaiser Permanente Care Management Institute. Colorectal cancer screening. Clinical practice guideline. Appendices 1-2. Oakland (CA): Kaiser Permanente Care Management Institute; 2006 Nov. 4 p.

Electronic copies: Not available at this time.

Print copies: Available from the Kaiser Permanente Care Management Institute, One Kaiser Plaza, 16th Floor, Oakland, CA 94612

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on July 9, 2007. The information was verified by the guideline developer on August 3, 2007.

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